

OCT 22 2004

Summary

510(k) Summary of safety and effectiveness

Date: 6/17/2004

Submission By:	JR Medical Technologies, Inc. 6650 Cottage Hill Road, Suite 307 Mobile, AL 36695
Manufactured by:	Shanghai Foshion Medical Instrument Co., Ltd. Buld.15, NO. 1515 Yuandong Rd(N) Fengxian District, Shanghai 201401 China
Contact:	John Rhim 251-895-0303 251-479-7777 Fax johnrhim@hotmail.com
Device Name:	CROMAX turbine handpiece
Common Name:	Handpiece, air-powered, dental
Classification Name:	Dental handpiece
Device Class:	Class I
Product Code:	76 EFB
Code of Federal Regulations:	21 CFR § 872.4200
Indications for Use:	The device is an air-powered dental handpiece for use in general dentistry.
Predicate Device Name:	T1 Line Dental Handpieces, K972436 and Rapidd Highspeed Dental Handpiece K003518.

Description of Device:

The CROMAX Turbine Handpiece is an air-driven high-speed dental handpiece. It has an air-driven turbine with appropriate power and speed for use with dental carbide burrs and diamond cutting instruments. Construction is stainless steel for corrosion resistance. It has water spray for cooling of the cutting burr. One model has push-button chucking mechanism to grip cutting instrument with ISO standard shanks.

The CROMAX Turbine Handpiece may be sterilized by the steam autoclave method. The bearing are sealed.

Technically supported and adopted key components of rotor and ball bearing from Bien-Air, Switzerland. Foshion produced CROMAX turbine handpiece and powered by Bien-Air.

Substantially Equivalence – Safety and Effectiveness:

CROMAX Turbine Handpiece is substantially equivalent to one or are air-powered dental handpieces currently marketed in the USA. The handpiece is constructed of materials of the same specifications as the predicate device to ensure biocompatibility. The handpiece conforms to applicable ISO standards.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 22 2004

J.R. Medical Technologies, Incorporated
C/O Mr. J. Harvey Knauss
Contract Consultant
Delphi Consulting Group
11874 South Evelyn Circle
Houston, Texas 77071-3404

Re: K041755
Trade/Device Name: CROMAX Turbine Handpiece
Regulation Number: 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: October 14, 2004
Received: October 18, 2004

Dear Mr. Knauss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number _____

Device Name: *CROMAX Turbine Handpiece*

Indications for Use: The device is an air-powered dental handpiece for use in general dentistry.

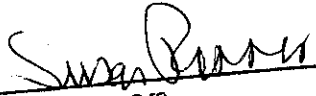
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: 16041735